penalty at an amount sufficiently close to or at the maximum permitted by §150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§150.323 Determining the amount of penalty—other matters as justice may require.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§150.325 Settlement authority.

Nothing in §§150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with §150.307 or to compromise on any penalty provided for in §§150.315 through 150.323.

§150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§150.343 Notice of proposed penalty.

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the HIPAA requirements that CMS has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which CMS based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with §150.347.

§150.345 Appeal of proposed penalty.

Any entity against which CMS has assessed a penalty may appeal that penalty in accordance with §150.401 *et seq.*

§150.347 Failure to request a hearing.

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in §150.343, CMS may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. CMS notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a

hearing in accordance with §150.405 unless the responsible entity can show good cause, as determined under §150.405(b), for failing to timely exercise its right to a hearing.

APPENDIX A TO SUBPART C OF PART 150—EXAMPLES OF VIOLATIONS

This appendix lists actions in the group and individual markets for which CMS may impose civil money penalties. This list is not all-inclusive.

NOTE 1: All cross-references to sections of the Code of Federal Regulations are cross-references to sections in parts 144, 146, or 148 of this subchapter.

NOTE 2: Except as otherwise expressly noted, all references to non-Federal governmental plans refer to non-Federal governmental plans that are *not* exempt from HIPAA requirements (as defined in §150.103) under section 2721(b)(2) of the PHS Act and §146.180.

I. Basis for Imposition of Civil Money Penalties—Actions in the Group Market

a. Failure to comply with the limitations on pre-existing condition exclusions (§146.111).

Violations of the limitations on pre-existing condition exclusions, set forth in §146.111, includes those circumstances in which a non-Federal governmental plan or health insurance issuer offering group health insurance coverage does the following:

(1) Imposes a preexisting condition exclusion period that exceeds 12 months or, in the case of a late enrollee, 18 months, from the enrollment date (the first day of coverage or the first day of the waiting period, if any).

(2) Fails to reduce a pre-existing condition exclusion period by creditable coverage as provided in §§146.111(a)(1)(iii) and 146.113.

(3) Imposes a pre-existing condition exclusion period without first giving the two written notices required in §§146.111(c) and 146.115(d). The first notice is a general notice to all plan participants of the existence and terms of any pre-existing condition exclusion under the plan, and the rights of individuals to demonstrate creditable coverage. The notice should explain the right of an individual to request a certificate from a previous plan or issuer, if necessary, and include a statement that the current plan or issuer will assist in obtaining a certificate from a previous plan or issuer, if necessary. The second notice is required to be sent to any individual who has presented evidence of creditable coverage, and to whom a pre-existing condition exclusion period will be applied. This second notice informs the individual of the plan's determination of any pre-existing condition exclusion period, the basis for such determination, a written explanation of any appeals procedures established by the plan or issuer, and a reasonable opportunity to submit additional evidence of creditable coverage.

(4) Treats pregnancy as a pre-existing condition, as prohibited by §146.111(b)(4). For example, an issuer may not refuse to pay for prenatal care and delivery effective with the date maternity coverage began because the individual did not have maternity coverage at the time the pregnancy began.

(5) Imposes a pre-existing condition exclusion with regard to a child who enrolls in a group health plan within 30 days of birth, adoption, or placement for adoption.

(6) Imposes a pre-existing condition exclusion with regard to a child who was enrolled in another group health plan within 30 days of birth, adoption, or placement for adoption and who does not experience significant break in coverage.

(7) Uses a pre-existing condition look-back period that exceeds the six-month period ending on the enrollment date in violation of §146.111(a)(1) of this chapter.

(8) Determines whether a pre-existing condition exclusion applies by using a standard other than whether medical advice, diagnosis, care, or treatment was actually recommended or received during the look-back period. A determination that a reasonably prudent person would or should have sought medical care for the condition is an unacceptable standard by which to determine whether a pre-existing condition exclusion applies.

(9) Uses genetic information as part of the definition of pre-existing condition in the absence of a diagnosis of the condition related to the genetic information.

(10) Otherwise fails to comply with §146.111.

b. Failure to comply with the provisions relating to creditable coverage (§146.113).

Failure to comply with the §146.113 rules relating to creditable coverage includes those circumstances in which a non-Federal governmental plan or issuer offering group health insurance coverage does the following:

(1) Fails to treat all forms of coverage listed in §146.113(a) as creditable coverage.

(2) Counts creditable coverage in a manner inconsistent with the standard method described in §146.113(b) or the alternative method described in §146.113(c), if it elects to use the alternative method.

(3) Treats an individual with fewer than 63 consecutive days without creditable coverage as having a significant break in coverage in violation of §146.113(b)(2)(iii).

(4) Takes either a waiting period or an affiliation period into account when calculating a significant break in coverage, as prohibited by §146.113(b)(2)(iii).

(5) Otherwise fails to comply with §146.113.

c. Failure to comply with the provisions regarding certification and disclosure of previous coverage (§146.115).

Except as provided in paragraph (c)(b), the plan sponsor of a self-funded non-Federal governmental plan may not elect to exempt its plan from the requirements of this paragraph.

Failure to comply with the requirements in §146.115 regarding certification and disclosure of previous coverage includes those circumstances in which a non-Federal governmental plan or issuer offering group health insurance coverage does the following:

(1) Fails to ensure that individuals who request certification receive it.

(2) Fails to automatically provide certificates of creditable coverage promptly, either—

(i) When the individual ceases to be covered under the plan (whether or not COBRA continuation coverage is offered or elected); or

(ii) When the COBRA continuation coverage is exhausted or is terminated by the individual, if COBRA continuation coverage was offered and was elected.

(3) Fails to provide certificates of creditable coverage promptly upon request.

(4) Fails to provide the required information in certificates of creditable coverage.

(5) Fails to provide certificates of creditable coverage to dependents.

(6) Fails to accept other evidence of creditable coverage as provided in §146.115(c). (The plan sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan from the requirements of this paragraph (6)).

(7) Otherwise fails to comply with §146.115.

d. Failure to comply with the provisions regarding special enrollment periods (§146.117).

Failure to comply with the §146.117 requirements regarding special enrollment periods includes those circumstances in which an issuer or a non-Federal governmental plan does the following:

(1) Fails to permit employees and dependents to enroll for coverage if they satisfy the conditions of §146.117(a) or (b).

(2) Fails to provide coverage on a timely basis to individuals protected by a special enrollment period as provided in §146.117.

(3) Fails to provide the employee with a description of the plan's or issuer's special enrollment rules on or before the time the employee is offered the opportunity to enroll as provided in §146.117(c).

(4) Otherwise fails to comply with §146.117.

e. Failure to comply with the HMO affiliation period provisions (§146.119).

Failure to comply with the §146.119 affiliation period requirements includes those circumstances in which an HMO that offers group health insurance coverage does the following:

(1) Imposes a pre-existing condition exclusion period.

(2) Charges a premium for months in an affiliation period.

(3) Fails to impose an affiliation period uniformly without regard to any health status-related factor.

(4) Imposes an affiliation period that is longer than 2 months (or 3 months for late enrollees), or one that begins later than the enrollment date or does not run concurrently with any waiting period.

(5) Otherwise fails to comply with §146.119.

f. Failure to comply with the provisions regarding nondiscrimination (§146.121).

Failure to comply with the §146.121 prohibitions regarding nondiscrimination includes those circumstances in which an issuer or a non-Federal governmental plan does the following:

(1) Applies rules of eligibility (including continued eligibility) to enroll under the terms of the plan based any of the health-status related factors described in §146.121(a).

(2) Requires an individual as a condition of enrollment or re-enrollment to pay a higher premium than others similarly situated by reason of a health-status related factor of the individual or the individual's dependent.

(3) Otherwise fails to comply with §146.121.

g. Failure to comply with the provisions relating to benefits for mothers and newborns (§146.130) in States where the §146.130 standards are applicable.

Failure of an issuer or a non-Federal governmental plan to comply with the standards in §146.130 relating to benefits for mothers and newborns includes the following:

(1) Restricts benefits for a mother or her newborn to less than 48 hours following a vaginal delivery or less than 96 hours following a delivery by cesarean section, unless the attending provider decides, in consultation with the mother, to discharge the mother or newborn earlier.

(2) Fails to calculate the length of stay from the time of delivery when delivery occurs in a hospital, or from the time of admission when delivery occurs outside the hospital.

(3) Penalizes an attending provider for complying with the law.

(4) Offers incentives to an attending provider to provide care in a manner inconsistent with the provisions of §146.130.

(5) Denies the mother or newborn eligibility or continued eligibility to enroll under the plan to avoid complying with §146.130.

(6) Provides payments or rebates to mothers to encourage them to accept less than the minimum stay required.

(7) Requires an attending provider to obtain authorization to prescribe a hospital length of stay of up to 48 hours (or 96 hours) after delivery.

(8) Imposes deductibles, coinsurance, or other cost-sharing measures for any portion of a 48-hour (or 96-hour) hospital stay that are less favorable than those imposed on any preceding portion of the stay.

(9) In the case of a non-Federal governmental plan, fails to provide participants and beneficiaries with a statement describing the requirements of the Newborns' and Mothers' Health Protection Act of 1996, using the language provided at §146.130(d)(2), not later than 60 days after the first day of the first plan year beginning on or after January 1, 1999.

(10) Otherwise fails to comply with §146.130.

h. Failure to comply with the provisions pertaining to parity in the application of certain limits to mental health benefits in the large group market (§146.136).

Failure of a non-Federal governmental plan offered by a large employer or health insurance issuer offering health insurance coverage to large employers to comply with the §146.136 provisions pertaining to parity in the application of certain limits to mental health benefits (with respect to a plan that must comply with such provisions) includes the following:

(1) Sale of a product by a health insurance issuer that fails to comply with the mental health parity provisions of §146.136.

(2) Failure of a non-Federal governmental plan to comply with the annual and lifetime dollar limits provisions concerning mental health parity.

i. Failure to comply with the Women's Health and Cancer Rights Act of 1998 (section 2706 of the PHS Act, 42 U.S.C. 300gg–06).

j. Failure to comply with the provisions regarding guaranteed availability of coverage in the small group market (§146.150).

Failure to provide guaranteed availability in the small group market as provided in §146.150 includes those circumstances in which a health insurance issuer offering any health insurance coverage to group health plans in the small group market does the following:

(1) Fails to offer all products on a guaranteed availability basis to all small employers.

(2) Fails to define a small employer using the definition at §144.103, unless otherwise provided under State law; that is, generally an employer with between 2 and 50 employees.

(3) Fails to count as employees all individual employees that an employer wants to include in the group by applying a more restrictive definition of ''employee'' than is permitted by §144.103.

(4) Fails to accept all employee dependents who are qualified under the terms of the employer's group health plan.

(5) Sets agent commissions for sales to small employers so low as to discourage agents from marketing policies to, or enrolling, these groups so that a failure to offer coverage results.

(6) Unreasonably delays the processing of applications submitted by small employers, so that a break in coverage of more than 63 days results.

(7) Fails to offer to any small employer on a guaranteed availability basis any product that the issuer sells to small employers through one or more associations that are not bona fide associations, as defined in §144.103. The requirement to guarantee availability of such products to all small employers applies whether or not the small employer is a member of, or could qualify for membership in, that association.

(8) Otherwise fails to comply with §146.150.

k. Failure to comply with the requirements regarding guaranteed renewability in either the large or small group market (§146.152).

Failure to provide guaranteed renewability of coverage as provided in §146.152 includes those circumstances in which a health insurance issuer offering health insurance coverage to a group health plan in the small or large group market does the following:

(1) Fails to renew or continue in force coverage at the option of the plan sponsor unless one of the specific exceptions in §146.152(b) is met.

(2) Fails to follow the requirements as described in §146.152(c)–(e) relating to the discontinuance of a particular product or withdrawal from the market of a particular product.

(3) Fails to renew coverage of an individual employer who has been a member of an association when the individual employer ceases to be a member of the association, unless it is a bona fide association as defined in §144.103, and the issuer terminates coverage for all former members on a uniform basis.

(4) Fails to act uniformly if the issuer cancels coverage.

(5) Otherwise fails to comply with §146.152.

l. Failure to comply with the requirements relating to disclosure of information (§146.160).

Failure to make reasonable disclosure as provided in §146.160 includes those circumstances in which an issuer offering group health insurance coverage to a small employer, as defined in §144.103, does the following:

(1) Fails to disclose all information concerning all products available from the issuer in the small group market as defined in §144.103.

(2) Otherwise fails to comply with §146.160.

II. Basis for Imposition of Civil Money Penalties—Actions in the Individual Market

a. Failure to comply with the requirements regarding guaranteed availability of coverage (§148.120).

In States that are not implementing an acceptable alternative mechanism described in §148.128, failure to provide guaranteed availability with no preexisting condition exclusion period as provided in §148.120 includes those circumstances in which an issuer does the following:

(1) Fails to provide to eligible individuals, on a guaranteed availability basis, at least one of the following:

(i) Enrollment in all individual market policies it actually markets.

(ii) The two most popular policies described in §148.120(c)(2).

(iii) Two representative policy forms as described in §148.120(c)(3).

(2) Imposes any preexisting condition exclusion or affiliation period on eligible individuals under any policy that it sells on a guaranteed availability basis.

(3) Sets agent commissions for sales to eligible individuals so low as to discourage agents from marketing policies to, or enrolling, these individuals so that a failure to offer coverage results.

(4) Unreasonably delays the processing of applications submitted by eligible individuals.

(5) Fails to offer to any eligible individual as defined in §148.103 (on a guaranteed availability basis with no preexisting condition exclusions) any product the issuer sells to individuals through one or more associations that are not bona fide associations, as defined in §144.103, unless the issuer has designated at least two other products (as its two most popular or its two representative policies) that it will sell to eligible individuals.

(6) Denies an eligible individual a policy on the basis that the individual has had a significant break in coverage even though a substantially complete application was filed on or before the 63rd day after the prior group coverage ended.

(7) Otherwise fails to comply with §148.120.

b. Failure to comply with the requirements regarding guaranteed renewability of coverage (§148.122).

Failure to provide guaranteed renewability as provided in §148.122 includes those circumstances in which an issuer does the following:

(1) Fails to renew or continue in force coverage at the option of the individual, unless one of the specific exceptions in §148.122 is met.

(2) Fails to follow the requirements relating to the discontinuance of a particular product or withdrawal from the market of a particular product as described in §148.122(d).

(3) Fails to continue coverage at the option of the individual after the individual becomes eligible for Medicare.

(4) Fails to renew coverage for an individual who has been a member of an association when the individual ceases to be a member of the association, unless the association is a bona fide association as defined in §144.103 and the issuer uniformly terminates coverage for all former members.

(5) Otherwise fails to comply with §148.122.

c. Failure to comply with the requirements regarding certification and disclosure of coverage (§148.124).

Failure to comply with the requirements of §148.124 regarding certification and disclosure of previous coverage includes those circumstances in which an issuer does any of the following:

(1) Fails to provide automatic certificates of creditable coverage promptly.

(2) Fails to disclose the required information in certificates of creditable coverage as provided in §148.124(b).

(3) Fails to provide certificates of creditable coverage to dependents who are insured in the individual market and whose coverage ceases under an individual policy.

(4) Fails to credit coverage or establish eligibility as provided in §148.124 solely because the individual is unable to obtain a certificate. This includes failing to accept, acknowledge, consider, or otherwise use other evidence of creditable coverage described in §146.115(c) submitted by, or on behalf of, an individual to establish that person is an eligible individual.

(5) Otherwise fails to comply with §148.124.

d. Failure to comply with the requirements regarding determination of an eligible individual (§148.126).

Failure to determine, as provided in §148.126, that an applicant for health insurance is an eligible individual includes those circumstances in which an issuer does the following:

(1) Fails to identify eligible individuals, to provide information regarding all coverage options, and to issue policies promptly.

(2) Requires eligible individuals to specify their desire to invoke the requirements of part 148 or to explicitly request their rights under the law in order to obtain information about products available to them.

(3) Otherwise fails to comply with §148.126.

e. Failure to comply with the standards relating to benefits for mothers and newborns (§148.170).

In States where the §148.170 standards are applicable (see §148.170(e)), failure to comply with the §148.170 standards relating to benefits for mothers and newborns includes those circumstances in which a health insurance issuer does the following:

(1) Restricts benefits for a mother or her newborn to fewer than 48 hours following a vaginal delivery or fewer than 96 hours following a delivery by cesarean section, unless the attending provider decides, in consultation with the mother, to discharge the mother or newborn earlier.

(2) Fails to calculate the length of stay from the time of delivery when delivery occurs in a hospital, or from the time of admission when delivery occurs outside the hospital.

(3) Requires an attending provider to obtain authorization to prescribe a hospital length of stay of up to 48 hours (or 96 hours, if applicable) after delivery.

(4) Imposes deductibles, coinsurance, or other cost-sharing measures for any portion of a 48-hour (or 96-hour, if applicable) hospital stay that are less favorable than those imposed on any preceding portion of the stay.

(5) [Reserved]

(6) Penalizes a provider for complying with the law.

(7) Offers incentives to a provider to provide care in a manner inconsistent with the provisions of §148.170 to avoid complying with §148.170.

(8) Denies the mother or newborn eligibility or continued eligibility solely to avoid the requirements of §148.170.

(9) Provides incentives to mothers to encourage them to accept less than the minimum stay requirement.

(10) Fails to provide participants and beneficiaries with a statement describing the requirements of the Newborns' and Mothers' Health Protection Act of 1996, using the language provided at §148.170 (d)(2), not later than March 1, 1999.

(11) Otherwise fails to comply with §148.170.

f. Failure to comply with the Women's Health and Cancer Rights Act of 1998 (section 2752 of the PHS Act, 42 U.S.C. 300gg–52) and any additional implementing regulations.

Subpart D—Administrative Hearings

§150.401 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services.

Filing date means the date postmarked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone hearing.

Party means CMS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to §150.343.

§150.403 Scope of ALJ's authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedure Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with §150.407(a), within 30 days after the date of issuance of either CMS's notice of proposed assessment under §150.343 or notice that an alternative dispute resolution process has terminated. The request for hearing should be addressed as instructed in the notice of proposed determination. ''Date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§150.407 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.